1623

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Formal Response to the Office Detailed Action Dated April 15, 2003

Your Ref. Application/Control Number: 09/944,564
Art Unit: 1623

The Examine: Patrick T. Lewis, PhD

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please note that this signed covering letter was refaxed after the response and annexes.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/944,564	09/04/2001	1623	0.00			24	15

CONFIRMATION NO. 8476

FILING RECEIPT

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AL-JASSIM Rawaa
24 W. 601 Birdsong Court
Naperville, IL 60540

Date Mailed: 10/09/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Nida Abdul-Ghani Nassief, Doha, IRAQ;

Domestic Priority data as claimed by applicant

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** SMALL ENTITY **

Title

Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils

Preliminary Class

514

Official Response to the USPTO Detailed Action Dated April 15, 2003

Priority

1. No comments

Information Disclosure Statement

2. May I ask the examiner to consider them.

Introduction:

The Drug Manufacturing Company Cantabria is aware of my patent application, and considers me as the inventor (Annex 1).

As the applicant, my response to the comments of the examiner's communication related to disposition of the above identified application claims will be through:

A. Argument or reasoning
B. New evidence in the form of printed publication
C. Demonstration by a preponderance of evidence that it is more likely than not that one of ordinary skill in the art would consider the asserted utility credible (letters from the FDA, Annex 2).
D. Amendment to the claims

May I request continued examination of my application?

As an inventor prosecuting the application myself, may I request the examiner to draft claims on my behalf?

Also, requesting amendment of the specification

Claim Objections

3. Claim 9-13 and 15-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim.

Response: The above mentioned multiple dependent claims are amended to a proper form.

Claim Rejections – 35USC §101

4. 35USC 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

5. Claims 1, 2, 7, 17, 19, 22, and 24 are rejected under 35USC §101 because the claimed recitation of a use, without setting forth any steps involved in the process, result in an improper definition of a process, i.e., results in a claim which is not a process claim under 35USC §101.

Response:

35 U.S.C§ 101 teaches that: it has two purposes. First § 101 defines which categories of inventions are eligible for patent. Second, § 101serves to insure that patents are granted on only those inventions that are "useful."

Useful = "practical utility" or "specific utility"

"practical utility" is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provide some immediate benefit to the public.

Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a "specific" utility

Under the title of: Legal Analysis Supporting Utility Examination Guidelines,

General Principals Governing Utility Rejections (MPEP 2107 et al.), C. Therapeutic or Pharmacological Utility: it is stated that

Courts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacologic use provides an "immediate benefit to the public" and thus satisfies the utility requirement. As the CCPA held in Nelson v. Bowler.

(Annex c, 2 pages, http://www.uspto.gov/eeb/offices/pac/dapp/utility.htm)

Claim 1: AS a pharmaceutical invention the steps involved in the process claimed includes: (1) the chemical name of the compound administered, (2) what constitutes effective quantities for administration, (3) duration of treatment, route of administration, and (4) the main outcome measures in a human clinical trial that proves its "usefulness in a real life". (In relation to allergy Stage III, page 11. In asthma stage IV, page 12 through 14 and, long term follow up page 16 of the Best Mode of Carrying Out the Invention). The claim will be amended to involve the steps if necessary.

May I refer to **Ex parte** Raymond W. Kosley JR., Larry Davis and Veronica Taberna, Appeal No. 1997-2188, Application 08/137, 440. Page reference as appear on a print from the Internet. (http://www.uspto.gov/web/offices/dcom/bpai/decisions/fd971288.pdf)

Claim 28. A pharmaceutical composition which comprises a pharmaceutically acceptable carrier and a acetylcholinesterase inhibiting amount of the compound of claim 1.

Claim 29. A method of treating memory dysfunction characterized by decrease cholinergic [Sic, Cholinergic] function which comprises administering to a mammal an acetylcholinesterase

inhibiting amount of the compound of claim 1.

Claim 30. A method of treating memory dysfunction characterized by decreased cholinergic function with [Sic, with] 6-0-demethylgalantthamine which comprises administering to a mammal an acetyl-cholinesterase inhibiting compound of claim 4 (pages 4-5).

The first method requires administering to a mammal with memory dysfunction characterized by decreased cholinergic function an amount of the compound of claim 1 sufficient to inhibit the formation in the mammal of the enzyme AchE (last paragraph, page 8).

The examiner also expresses his belief that the prior art on which he has relied established that there was, at the time of appellants' invention, no known cure or even treatment for Alzheimer's disease. In the first instance, as we have stated above, appellants do not claim either a cure of or even treatment for Alzheimer's disease but claim a method for treating a specific type of memory dysfunction. Secondly, the operative claim term used in "treating" by administration of the claimed compounds to a mammal. We consider the term "treating" to encompass a method which results in the mitigation of any symptom of the condition being treated but not to encompass "curing" the condition. Persons, who suffer from allergies such as hay fever, for example "treat" their symptoms with antihistamines and, yet, still have the underlying allergy (page 16).

Appellants disclose how the claimed compounds may be administered, what constitutes effective quantities for administration and the form in which the compounds may be administered (page 8, line 27 through page 10, line 3 of the specification). Possessed of this disclosure, we have no doubt but that the skilled routineer would be able to prepare and use the claimed compounds in the manner disclosed above (page 17).

Claim 2. Is withdrawn.

Claim7. The process is described (Stage V, last paragraph of page 16 through first paragraph of page 17 of the Best Mode of Carrying Out the Invention).

Claim 17. Withdrawn

Claim 19. Withdrawn

Claim 22. The process is described in page 17, paragraph 2 of the Best Mode of Carrying Out the Invention.

Claim 24. Withdrawn

Claim Rejections – 35USC §112

6. The following is a quotation of the first paragraph of 35USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 5, and 17-24 are rejected under 35USC 112, first paragraph, because the specification, while being enabling for method of treating allergy/asthma, influenza, and the common cold comprising the administration of glycophosphopeptical, does not reasonably provide Enablement for method for the prophylaxis of allergy/asthma comprising the administration of glycophosphopeptical; methods for the treatment of any diseases caused by type I IgE-mediated hypersensitivity reaction comprising the administration of glycophosphopeptical; or methods for the treatment and/or prophylaxis of any viral respiratory tract infection, urinary tract infection, pelvic inflammatory diseases, Crohn's disease, facial palsy, or diseases characterized by a body immune defensive mechanism comprising the administration of any Th1 stimulating agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in In re Wands, 858F.2d 731, 737,8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of Enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

Response:

In relation to "enablement" for method for the prophylaxis of allergy/asthma: the term prophylaxis in this patent application was meant to describe the "therapeutic category" of this treatment rather than an additional claim. Preventive or controller medications in asthma and allergy, including corticosteroids, are those that control the underlying immunological disorder, they have a slow onset of action (days). The clinical response to corticosteroids preventive therapy was described by solomon Solis-cohen in 1890, the anti-asthma action of maintenance therapy with dried bovine adrenal glands was described as "**the constant dyspnoea first disappeared, the paroxysmal nocturnal attack became less frequent and less sever. Recovery was not rapid but was continuos**" (Ref: Persson C G A. In vivo veritas: the continuing importance of discoveries in complex biosystem. Thorax 1996; 51: 441-443).
In response to the examiner's comments the word "prophylaxis" will be all withdrawn from claims 1, 5, and 17-24.

THE "HOW TO USE" REJECTION UNDER § 112

The examiner's rejection of the claims as being based on a specification which fails to adequately teach "how to use" the claimed invention is a rejection under the so-called "Enablement" requirement of the first paragraph of 35 U.S.C. § 112. It is incumbent upon the examiner in rejecting claims under the first paragraph of 35 U.S.C. § 112, to establish a prima facie case of lack of Enablement. ****Moreover, in determining whether or not a disclosure is enabling, it has been consistently held that the Enablement requirement of the first paragraph of 35 U.S.C. § 112 requires nothing more than objective enablement. In re Marzocchi, 439 F.2d at 223, 169 USPQ at 369. In meeting the enablement requirement, an application need not teach,

and preferably omits, that which is well-known in the art. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

How such a teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims must be taken as complying with the first paragraph of 35 U.S.C. § 112 unless there is reason to doubt the objective truth of the statements relied upon therein for enabling support.

Factors to be considered in determining whether a disclosure would require "undue" experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of the routineer in the art, (7) the predictability or lack thereof in the art, and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737, USPQ2d 1400, 1404 (Fed. Cir. 1988).

In relation to "undue experimentation"

The factors include, but are not limited to:

1. **The breadth of the claims,**

Response: Some claims are withdrawn.

2. **The nature of the invention,**

Response: No comments

3. **The state of the prior art,**

The lack of novelty with regard to NON-PATENT DOCUMENTS cited by the examiner

Comment:

The first cited Ref. By the examiner: Ernst Mutschler et al. Drug Actions: Basic Principals and Therapeutic Aspects, CRC Press, pages 408-9, in the first paragraph: it describe that cortisol and cortisol derivatives suppresses almost all inflammatory reaction in the bronchial wall, it can be administered by inhalation and systemically. Also useful in crohn's disease (page 429- 430).

Response:

Corticosteroids are very well known for their side effect as growth retardation in children, bone demineralization, gastric ulcer, diabetogenic, and others. In asthma multiple daily doses are required in most patients leading to patient incompliance. In spite of that many asthmatic patients are uncontrolled.

The second cited Ref. By the examiner: John Walton et al. The Oxford Medical Companion, Oxford University Press, 1994, page 171: corticosteroids are defined as anti-inflammatory and immunosuppressant agent.

Response:

Immunosuppression is accompanied by many unwanted side effects. My invention is stimulating the immune system to treat the disease. Corticosteroids are **not** effective in sever asthma when administered orally every other day (Ref: British National Formulary. 35: 282-3 and 533. A joint publication of the British Medical Association and the Royal Pharmaceutical Society of Great Britian. March 1998). While my invention is a 5 days treatment that induce a long-term clinical remission (page 16)

The third cited Ref. By the examiner: Sanchez Palacios A. et al. Allergol Immunopathos (Mad), 1992, Vol 20(1), pages 35-39 (English abstract).

This publication that discloses the use of AM-3 for the treatment of asthmatic bronchitis:

Response:

This prior art target 'asthmatic bronchitis', which does not relate to the medical condition 'asthma'. Asthmatic Bronchitis denotes chronic bronchitis with features of bronchospasm that quickly responds to bronchodialtor therapy. The claim for novelty is made on the basis that no prior published documents specifically claim the use of Glycophosphopeptical for the treatment of asthma.

The differences between asthmatic bronchitis and asthma are clarified in the following statements:

1. Any shortness of breath was termed as asthma, as is the case with cardiac asthma, for example, (ref. 1).
2. Asthmatic bronchitis is defined as chronic bronchitis with features of bronchspasm that quickly responds to bronchodialtor therapy and this shows clearly that it is a different medical entity (ref. 1).
3. Asthmatic bronchitis is one of many other conditions that are included in the differential diagnosis of asthma (ref. 2). Therefore it is quite clear that we are referring to two separate conditions.

The 'Material y Metodos' of this publication:

Additional evidence that asthmatic bronchitis is different from 'asthma', comes from the material and method section of D6. Page 39 column 1, the first paragraph: patients selected were 40 children with no atopy (i.e. no genetic predisposition to type I hypersensitivity reaction, asthma and allergy), they have clinical respiratory infection of the bronchi especially y/o asthmatica with negative skin test for aero-allergen and normal total IgE.

This suggests that they have excluded patients with the criteria of real asthma and allergy from the selection.

Also from table III, where, the treatment used are antibioticos, mucoliticos and antitusigenos; no anti-asthma drugs are mentioned.

References:

Ref.1: Current Medical Diagnosis and Treatment (APPELTON & LANGE) 1997, chapter 9, page 242, column 1(Annex 4).

Ref.2: Textbook of Medicine, Third Edition, edited by R.L.Souhami and J. Moxham (Churchill Livingstone), chapter 15, page 543, column 2. Diagnosis and Management, lines 4-6 (Annex 5).

4. The level of one of ordinary skill,

Response: No comment.

5. The level of predictability in the art,

The prior art teaches that there is no cure for asthma, but it can be treated and managed so that the asthma sufferer can live a normal life.

Response:

May I refer to two publications from World Health Organization that highlights the plight of asthma. The first is HELP. OUR CHILDREN BREATH, Press release WHO/92, 7 Dec 1998. The first paragraph: There are between 100 and 150 million people in the world, including many children, who do not take breath for granted. For them it can be a life-and-death struggle against recurrent attacks of breathlessness and wheezing caused by asthma. Each year, around 180 000 of these sufferers lose the battle and die of the disease (Annex 6)

The second is Bronchial Asthma, WHO Fact Sheet No. 206, Revised Jan. 2000, it detailed the human and economic burden and that experts are struggling to understand why rates worldwide are rising and that the way forward is by International action, among others) is to stimulate research into the causes of asthma to develop new control strategies ant treatment techniques Annex 7, 3 pages, statements underlined).

My invention fulfill the criteria of a research into the causes of asthma to develop new control strategies ant treatment techniques.

6. The amount of direction provided by the inventor,

What is meant by Th1 stimulating agents of this invention are **only** glycophosphopeptical and Nigella sativa,

7. The existence of working examples, and

Response:

In case of asthma and allergy, In addition to what have been mentioned by the examiner, may I add the following:

In addition to I and 2, there are 20 patients treated during the year 1999 (page 15, line 2), they are also mentioned in page 15, table 1, glycophosphopeptical treated patients (total asthmatic patients = 55). In a pharmaceutical discovery, this is sufficient number! Annex 8 is Deputy Commissioner for Patent Examination Policy- MPEP Home Page, II Procedural Consideration Related to Rejection for lack of Utility, 4 pages), may I request the examiner to consider them in my case, as my patent application is related to this group.

The various symptom scores used in the follow up of the patients are important, and are routinely used in clinical research. In addition, the laboratory parameters represents the main outcome measures and are well known in the art. An example of a leading article is the following reference: Barnes J. P. Anti-IgE antibody therapy for asthma. The New England Journal of Medicine 1999 December 23; 341(26): 2006-8.

8. **The quantity of experimentation needed to make and/or use the invention**

Response:

Many of them has been withdrawn.

9. Claims 1-2, 5-8, 14, and 17-24 are rejected under 35U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

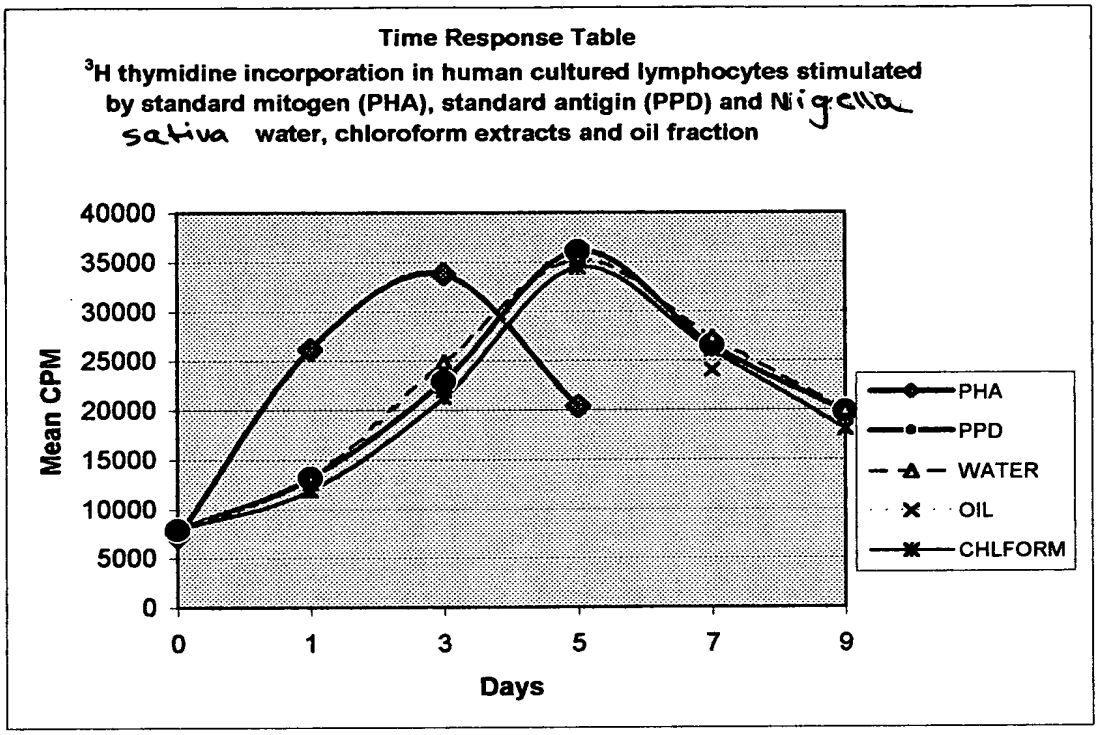
The claims are amended

10. Claims 1-2, 7, 17, 19, 22, and 24 provides for the use of glycophosphopeptical, pure seeds of Nigella sativa, or Th1 stimulating agents, but, since the claim does not set forth any steps involved in the method/processes, it is unclear what method/process applicant is intending encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Response:

In relation to Nigella Sativa, I am claiming this herbal treatment as a "mean of performing a function" which is a PPD-like activity (PPD derived from BCG), it has a vaccine-like property to treat the selected diseases. And the method as claimed for glycophosphopeptical.

The following graph is a representation of table 2, page 20 of the patent. PHA values are presented in the priority document tables (Time-response table for mitogen stimulation (PHA) of 10^6 lymphocytes). Note the distinct coincidence of results between PPD (Purified Protein Derivative of Bacillus Calmetti Gurein) and extracts from Nigella Sativa herb as shown in the following graph that appears in the next page.



11. Regarding claims 1-2, 5, and 17-24, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention . See MPEP § 2173.05(d).

It has been amended.

12. Regarding claim 4, the phrase" the claim 4 including a dosage regimen" renders the claim indefinite as it is unclear what the phrase is referring to. If applicant intends to limit the composition of claim 4, the claim should be amended to more clearly reflect applicant's intentions.

It has been amended.

13. Regarding claim 6, the phrase "preferably" renders the claim indefinite but it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

It has been amended.

14. Regarding claims 1-2, the phrase "allergy/asthma" is not clearly defined. The terms are not seen to be equivalent. If applicant intends for the phrase to be considered in an alternative fashion (i.e. allergy and/or asthma), the claims should be amended to more clearly reflect applicant's intentions.

It has been amended.

15. Regarding claims 1-2, 17, and 19, the phrase "treatment and/or prophylaxis" renders the claim indefinite. It is not readily clear from the disclosure as to how treatment **and** prophylaxis are achieved in a single process.

It has been amended.

16. The term "pure" in claim 7 is a relative term which renders the claim indefinite. The term "pure" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It has been amended.

17. Claim 8 recites the limitation "pharmaceutical composition as claimed in claim 6" in line 1. There is insufficient antecedent basis for this limitation in the claim.

It has been amended.

18. Claim 14 is drawn to the manufacture of a diagnostic kit; however, no active steps are set forth that would apprise one of ordinary skill in the art of the metes and bounds of the claim.

It has been deleted.

Claim Rejections – 35USC §102

19. Claims 1-8, 17-19, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanchez Palacios A. et al. Allergol Immunopathos (Madr), 1992, Vol 20(1), Pages 35-39 (Sanchez).

Response:

Answered in the prior art.

Dear Examiner: May I refer to the following International and USA patents that are within the scope of my invention and claim the same broad claims.

The invention is related to an immune cell that defend the body against many diseases.

Title: Immunostimulatory Nucleic Acid Molecules. International Publication No.: WO 98/18810.

Title: Immunostimulatory oligonucleatides, Composition thereof, and Method of Use Thereof. International Publication No.: WO 98/55495.

Title: Nigella Sativa as a Medicinal Treatment. International Publication No.: WO 95/05839.